

## REMARKS

Claims 12-22 are pending in this application, with claims 12 and 22 being the only independent claims.

Claims 12-16, 18-20, and 22 have been rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,713,867 to Morris (“Morris”) in view of U.S. Patent No. 5,431,676 to Dubrul et al. (“Dubrul”). Claim 17 has been rejected under 35 U.S.C. §103(a) as unpatentable over Morris in view of Dubrul, and further in view of U.S. Patent No. 6,939,327 to Hall et al. (“Hall”). Claim 21 has been rejected under 35 U.S.C. §103(a) as unpatentable over Morris in view of Dubrul, and further in view of U.S. Patent No. 4,687,469 to Osypka (“Osypka”).

### Rejection of claims 12-16, 18-20, and 22 under 35 U.S.C. §103(a)

The Office Action states that the combination of Morris and Dubrul teaches all of Applicants’ recited elements.

Independent claim 12 is directed to a dilatation system for dilating an existing tissue passage in a body. The dilatation system includes a dilatation pin that includes a distal end and a diameter which increases proximally from the distal end, and a tubular guide sleeve that has a length, a thickness, and an inside diameter, which corresponds to the diameter of the dilatation pin at the distal end. The tubular guide sleeve is intrinsically stable in an empty state to maintain the existing tissue passage and is separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve.

Morris discloses an introducer system that includes a sheath (61) that is kink resistant, which is used for the insertion of pacemaker leads into the venous system. The kink resistance permits the sheath (61) to be bent while still allowing a lead to be introduced therethrough. The

kink resistance is provided by a composite construction of the sheath (61). The sheath (61) has at least one integral reinforcing fiber. The reinforcing fibers are provided in a braided configuration. The sheath (61) is constructed to be readily split using a slitter (67) in a longitudinal direction and permits the sheath (61) to be removed from the venous system without having to withdraw the sheath (61) over an end of a pacemaker lead (see col. 5, lines 57-62 of Morris). Morris further discloses that a dilator (66) and the sheath (61) are inserted together into an incision (see col. 4, lines 32-40 of Morris). The dilator (66) is withdrawn from the sheath (61) and the central lumen (65) in the sheath (61) provides access to the vessel (col. 5, lines 23-26).

Accordingly, Morris fails to teach or suggest that the sheath (61) is “separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve”, as recited in Applicants’ claim 12.

In contrast to Applicants’ recited invention, after the pacemaker leads of Morris have been introduced into a patient, the sheath (61) must remain intact when the dilator (66) is removed and must be removed after insertion of the leads without removing the leads. This is only possible by destroying/splitting the sheath (61). Morris discloses using a separate cutting element (67) to open/split the sheath (61) along its longitudinal axis. Therefore, Morris teaches that an additional, special cutting element (67) is required for opening the sheath (61). Conversely, Applicants’ recited invention does not require a special cutting element to split the sleeve. Instead, the sleeve recited in Applicants’ claim 12 separates over the entire length when a dilatation pin is inserted.

Since Morris discloses that a cutting element is required to split or open the sheath, Morris fails to teach or suggest that the sheath (61) is “separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide

sleeve", as recited in Applicants' claim 12.

Dubrul fails to teach or suggest what Morris lacks. Dubrul discloses a device for providing percutaneous access to an internal operative site during a surgical procedure. As shown in Figs. 1, 4, and 9, the device includes an elongate dilation member 10 (which is to be dilated), at least one expansion member 12 for dilating the dilation member 10, and a trocar valve 16 (col. 9, lines 1-4). The dilation member 10 comprises a tubular braid 20 with braid filaments, in particular a mesh of individual non-elastic filaments (col. 6, lines 53-57). The tubular braid 20 is covered with a removable sheath 30 having a handle 32 at its proximal end (col. 9, lines 22-24). After the dilation member 10 has been placed in the opening of the human body, the expansion member 12 can be inserted into the dilation member 10 causing radial expansion of the tubular braid 20. The expansion member 12 will optionally split the sheath 30 upon insertion (col. 11, lines 12-29). The sheath 30 protects the tubular braid 20 during initial insertion of the dilation member 10 into the body of the patient, but is removed from the braid 20 after the dilation member 10 is in place. Preferably, the sheath 30 is weakened along an axial line to facilitate splitting of the sheath 30 at some point during the procedure (col. 7, lines 14-19).

However, Dubrul fails to teach or suggest a tubular guide sleeve "being intrinsically stable in an empty state to maintain the existing tissue passage and being separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve", as recited in Applicants' independent claim 12. The tubular guide sleeve recited in Applicants' independent claim 12 can thus first maintain the opening of the body without any additional support elements, and the entire guide sleeve can then be completely removed from the opening after the dilatation pin has been inserted.

In contrast to Applicants' recited invention, the only stable element in the device of Dubrul, which maintains the opening once the dilation member 10 is inserted, is the tubular braid 20. The protective sheath 30, however, is not intrinsically stable at all. On the other hand, the tubular braid 20 is not separable along a line and remains within the body opening during treatment. Therefore, the device taught by Dubrul differs substantially from the device recited in Applicants' claim 12.

In view of the foregoing, Morris and Dubrul, whether taken alone or in combination, do not teach or suggest the subject matter recited in Applicants' independent claim 12. Specifically, Morris and Dubrul do not teach or suggest a dilatation system for dilating an existing tissue passage in a body comprising a tubular guide sleeve being intrinsically stable in an empty state to maintain the existing tissue passage and being separable over the entire length and thickness along at least one line upon insertion of the dilatation pin into the tubular guide sleeve, as recited in Applicants' independent claim 12. Accordingly, independent claim 12 is patentable thereover under 35 U.S.C. §103(a).

Independent claim 22 recites limitations similar to independent claim 1 and is therefore deemed to be patentably distinct over Morris and Dubrul for at least those reasons discussed above with respect to independent claim 12.

Claims 13-16, 18-20, which depend directly or indirectly from the independent claim 12, incorporate all of the limitations of independent claim 12 and are therefore deemed to be patentably distinct over Morris and Dubrul for at least those reasons discussed above with respect to independent claim 12.

Rejection of claim 17 under 35 U.S.C. §103(a)

The Office Action states that the combination of Morris, Dubrul, and Hall teaches all of Applicants' recited elements.

As previously discussed, Morris and Dubrul do not teach or suggest the subject matter recited in Applicants' independent claim 12.

Because Morris and Dubrul do not teach or suggest the subject matter recited in independent claim 12, and because Hall does not teach or suggest the elements of claim 12 that Morris and Dubrul are missing, the addition of Hall to the reference combination does not remedy the non-obviousness of the claim.

Claim 17, which depends directly from independent claim 12, incorporates all of the limitations of independent claim 12 and is therefore deemed to be patentably distinct over Morris, Dubrul, and Hall for at least those reasons discussed above with respect to independent claim 12.

Rejection of claim 21 under 35 U.S.C. §103(a)

The Office Action states that the combination of Morris, Dubrul, and Osypka teaches all of Applicants' recited elements.

As previously discussed, Morris and Dubrul do not teach or suggest the subject matter recited in Applicants' independent claim 12.

Because Morris and Dubrul do not teach or suggest the subject matter recited in independent claim 12, and because Osypka does not teach or suggest the elements of claim 12 that Morris and Dubrul are missing, the addition of Osypka to the reference combination does not remedy the non-obviousness of the claim.

Claim 21, which depends directly from independent claim 12, incorporates all of the limitations of independent claim 12 and is therefore deemed to be patentably distinct over Morris, Dubrul, and Osypka for at least those reasons discussed above with respect to independent claim 12.

Conclusion

In view of the foregoing, reconsideration and withdrawal of all rejections, and allowance of all pending claims is respectfully solicited.

Should the Examiner have any comments, questions, suggestions, or objections, the Examiner is respectfully requested to telephone the undersigned in order to facilitate reaching a resolution of any outstanding issues.

Respectfully submitted,

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